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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,026	10/06/2000	Anthony Louis Devico	11076-002001	3193

24239 7590 03/15/2007  
MOORE & VAN ALLEN PLLC  
P.O. BOX 13706  
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EXAMINER
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BOESEN, AGNIESZKA

ART UNIT	PAPER NUMBER
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1648

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/15/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No. 09/684,026	Applicant(s) DEVICO ET AL.	
	Examiner Agnieszka Boesen	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-9, 11, 13-16, 24, 34, 35, 37, 38, 40-46, 49-57, 60-63, 65 and 73-86 is/are pending in the application.
- 4a) Of the above claim(s) 34, 35, 37, 38, 40-46, 49-57, 60-63, 65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-9, 11, 13-16, 24 and 73-86 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### DETAILED ACTION

The Amendment filed December 15, 2006 in response to the Office Action of September 15, 2006 is acknowledged and has been entered. Claims 1-3, 6-9, 11, 13-16, 24, and 73-86 are under examination.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Rejection of claims 1 and 74 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** in view of Applicant's amendment.

#### New rejection in view of Applicant's amendment.

**Claims 1-3, 6-9, 11, 13-16, 24, and 73-85 under 35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims have been amended to recite, "truncated and modified full length reference sequence of the chimeric polypeptide has at least 95% identity to the full length reference sequence or truncated sequence and exhibits similar functionality thereof". The recitation of "exhibits similar functionality thereof" renders the claims indefinite. The skilled artisan would not know how to determine "similar functionality" without a definition of the function that is desired, or a way of determining whether the function meets the requirements for "similar". The

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metes and bounds of the claims cannot be determined without a clear definition of the recited terms. Clarification and correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Rejection of claims 1-3, 6-9, 11, 13-16, 24, and 73-85 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement **is maintained**.

The claims have been amended to recite that the truncated and modified full length reference sequence of the chimeric polypeptide has at least 95% identity to the full length reference sequence or truncated sequence and exhibits similar functionality thereof. Applicant argues that claim 1 defines parameters that enable broader protein claims because the claim recites functional language and clearly defines the functionality of the chimeric polypeptides, including truncated and modified forms and their activity. Applicant further argues that one of skill in the art would be able to very easily determine if the claimed chimeric polypeptides have the ability to form an interacting intramolecular complex. Applicant argues that the Examples presented in the specification provide guidance for one skilled in the art to practice the current invention in its full scope. In response to Applicant's arguments, the Office's position is that without further guidance, one of skill in the art would be required to conduct an undue amount of experimentation in order to experimentally test if all possible chimeric structures, encompassed in the current claims, can in fact form an interacting intramolecular complex. Claim 1 recites functional language, however, the recitation of "the chimeric polypeptide has at least 95%

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identity to the truncated sequence and exhibits similar functionality thereof’ does not limit the claimed structure because it allows for a large number of possible sequences. There is no guidance in the specification with regard to how is the full-length sequence truncated. First, the skilled artisan would not know how to truncate the full-length sequence, and second the skilled artisan would not know which amino acids residues should be deleted in to achieve 95% identity to the truncated sequence. The truncated full-length sequence encompasses any sequence that has minimum of 7-12 amino acids. Additionally, the recitation of “exhibits similar functionality thereof” is indefinite as discussed under 35 U.S.C. 112, second paragraph. Thus the asserted functional limitation recited in the claims does not limit the undefined structure of the claimed chimeric polypeptides. Applicant did not provide guidance as to how the chimeric polypeptide should be truncated. The HIV gp120 coat protein is about 140 amino acids in length, therefore there would be at least one hundred possible truncated versions of the coat protein itself without considering a surface receptor polypeptide comprised within the claimed chimera. Because the current specification does not provide guidance as to how the components of the claimed chimera should be truncated to preserve the desired functionality of the chimera, and because it would require an undue amount of experimentation in order to determine what kind of truncations are permissible, one of skill in the art would be unable to practice the invention to the full extend as claimed. For these reasons the rejection is maintained.

***Conclusion***

Applicant's amendment necessitated the new ground of rejections presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.

3/13/2007

Stacy B. Chen 3/13/07